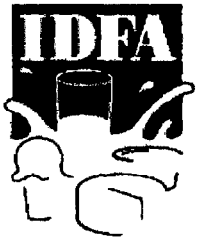

International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

April 4, 2003

Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Subject: Docket No. 02N-0278 - Prior Notice of Imported Food

To the Dockets Management Branch:

The International Dairy Foods Association (IDFA) is the Washington, D.C.-based organization representing the nation's dairy processing and manufacturing industries and their suppliers. IDFA is composed of three constituent organizations: the Milk Industry Foundation (MIF), the National Cheese Institute (NCI) and the International Ice Cream Association (IICA). Its 500-plus members range from large multinational corporations to single-plant operations, and represent more than 85% of the total volume of milk, cultured products, cheese, and ice cream and frozen desserts produced and marketed in the United States - an estimated $70 billion a year industry.

IDFA strongly supports the overall concept and provisions of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act), and the Food and Drug Administration's (FDA) critical role and goal of ensuring the safety and wholesomeness of the American food supply and maintaining consumer confidence. IDFA offers the following comments regarding the FDA's proposed regulation on prior notice of imported food published in the Federal Register on February 3, 2003. The issues addressed in these comments are:

1. The volume of requested registration information.
2. FDA's interpretation of the term "food."
3. Data collection, techniques.
4. Enforcement Discretion
5. Exemption for Research and Development Foods
6. Product identity, topping off shipments
7. Effect of Amendment to follow
8. Different modes of transportation

9. Cut off time for prior notices

Issue #1 – The volume of requested information.
In the Bioterrorism Act, Congress states the regulation shall require the submission of information necessary to notify the Secretary of six expressly identified data elements. Those six elements are: 1) the article, 2) the manufacturer and shipper, 3) the grower (if known within the specified time in which notice is required), 4) the country of origin, 5) the country from which the article is shipped, and, 6) the anticipated port of entry.

While IDFA envisioned that FDA might need additional data not directly identified by Congress, we are concerned that FDA's broad approach may hinder FDA's ability to achieve its goals. The more data FDA collects, the more difficult the data will be able to understand, search, and maintain.

After FDA has experienced managing the basic information necessary to meet the needs of the Bioterrorism Act, FDA can and perhaps should consider, through rulemaking, additional data elements. Given the very short timeframe for FDA to implement the regulation, it will be in everyone's best interest for FDA to focus on immediate needs to meet the October 12, 2003 final rule publication deadline.

At a minimum, FDA should eliminate from its form information identified as: Importer, Owner, Consignee, Carrier 1, Carrier 2, and Carrier 3.

Issue #2 - FDA's interpretation the term "food."
For the purposes of the registration and prior notice of imported food regulations under the Bioterrorism Act, FDA proposes to define the term "food" as it does in the Federal Food Drug and Cosmetic Act (FFDCA), Section 201(f). Section 201(f) states "*The term "food" means (1) articles used for food or drink for man or other animals, (2) chewing gum, and (3) articles used for components of any such article.*"

FDA also is proposing to include some examples of products that are considered food under 201(f) of the act. These examples include, but are not limited to: fruits, vegetables, fish, dairy products, eggs, raw agricultural commodities for use as food or components of food, animal feed, including pet food, food and feed ingredients and additives, including substances that migrate into food from food packaging and other articles that contact food.

FDA should define food in a sensible manner that will result in an efficient and workable regulation. IDFA asserts that the proposed definition, that is, the acceptance of the previous definition of food is unworkable. Taken to its logical conclusion, this definition include not only those items traditionally understood as food, but also virtually all items that come into contact with a food during the processing or packaging, stretching the scope of the regulation beyond FDA's ability to enforce as well as expanding its reach so far as to undermine the intent and efficacy of the program the regulation intends to effect. For example, theoretically, trace molecular amounts of metals, or oxides of metal can migrate from stainless steel to a food product during food processing. Similarly, miniscule amounts of materials from conveyors, cutting boards, utensils, piping and in all

likelihood millions of other items can also be transferred or migrate into a food during processing. The rule as proposed could cover virtually every material that ever contacts food.

As an alternative, IDFA urges FDA to adopt a risk based scheme. If the information being collected will not assist in protecting the safety and security of the food supply, it should not be collected because, it will instead hinder rather than help.

As indicated in IDFA's separate comments filed in response to the proposed regulation on Registration, FDA should focus accomplishing the goals of the Bioterrorism Act, without encumbering itself with unnecessary details competing for limited FDA resources. Therefore, the acid test should be to require prior notice those food items that could be used to contaminate the food supply.

Since resources are finite, every dollar and minute FDA employees spend tracking unnecessary information are dollars and minutes that FDA could have used to protect the US food supply. IDFA emphatically encourages FDA to give utmost consideration to necessary elements, and eliminate anything not relevant and which will detract from meaningful consideration of where realistic and tangible risks lie.

Issue #3 - Data collection, techniques.
In general, IDFA would suggest using a drop down fields for any data fields that contain a finite and known set of possible entries, for example, country or state. This will preclude variants of the same country and misspellings.

On page one of the data form, FDA has a box that states "Mandatory Information" and a box that states "Mandatory if applicable." IDFA has been unable to ascertain from the form or the text of the proposed regulation what these references are intended to convey. IDFA requests that FDA eliminate these references or make clear what they are referring to.

On page two of the data form, FDA uses the label "Trade/brand name." This is confusing. A trade name is the name under which a business operates. Frequently, it is referred to as a "doing business as" (dba) name. A brand name is the name that is given to a product. While there may be overlap, they are not interchangeable. Inasmuch as the request is being made under the header "Product Identity," the trade or dba name should not be requested. The form should request "Brand Name" only. While FDA may have chosen to refer to this area in a manner that was identical to the way that US Customs Service, IDFA would suggest that the propagation of this technical inaccuracy would be a mistake.

Issue #4 - Enforcement Discretion
IDFA is concerned that in the first months after the effective date of the final regulation, the regulated community and FDA may make many mistakes. We envision that this has the potential to shut down ports of entry and could result in millions of dollars worth of goods being lost, damaged or perishing before they can be approved for entry. Ports of entry are already having a difficulty processing goods in a timely manner due to

additional security measures. When the new requirements of prior notice go into effect, the burden at the ports will significantly increase. IDFA urges FDA to be cognizant of this potential scenario and consider the flexibility FDA has which can be used to alleviate problems when they arise. In essence, we urge FDA to understand and to use its discretionary enforcement authority to ensure that the flow of goods into this country is maintained during what we expect will be a few difficult months.

Issue #5 - Exemption For Research and Development Foods.

Many food processors receive research and development (R&D) ingredients and foods from foreign companies. IDFA suggests that FDA should create a de minimis exemption in the prior notice regulation for samples used for research and development that are imported into the US. In essence, small R&D shipments of ingredients are unlikely to present a risk associated with a security threat. This is particularly true because the end product that is made with R&D samples is not typically put into the stream of commerce for public consumption. Further, even if some of that product were to reach the public, it would have only done so after significant scrutiny of the product. To establish limitations so this proposed exemption is not used as a loophole by unscrupulous individuals, IDFA would recommend that FDA limit the proposed R&D sample exemption to shipments with a net weight of 50 pounds or less.

Issue #6 - Product Identity, Topping Off Shipments

FDA is correct in identifying the topping off practice as an important area for comments; the practice is reasonably common. IDFA is concerned that FDA has created considerable uncertainty as to the type of topping off allowed. FDA appears to contend that as long as topping off is done with the addition of a food item, that is acceptable; However, if the additional item is not covered by the earlier prior notice, it would require a separate prior notice. Given the specificity of prior notices and FDA product codes, these proposed requirements may negate the feasibility of topping off shipments.

Consider a shipment of chocolate ice cream originating in Canada (product code 13 A Y T 03 - ice cream, not vanilla flavored), destined for the US. FDA's proposal requires prior notice by noon the day before arrival. At the end of the notice day, if a shipper decides to top off the shipment with a different flavor of ice cream, he would be permitted to do so as long as the additional ice cream is not vanilla flavored. Vanilla ice cream has a different code, 13 A Y T 01, and would require a separate prior notice given. IDFA knows that numerous other idiosyncrasies exist in the product code database that will exacerbate the problem.

To complicate matters further, FDA requires that different packaging sizes must utilize separate notices, the utility of which IDFA questions. Finally, it appears that FDA also considers the use of a different brand to require a separate notice, without sufficient justification. Given these factors, IDFA believes FDA's proposal effectively preclude the option to top off.

Issue #7 - Effect of Amendment to follow

IDFA is concerned with the effect of one of the last items on the prior notice form, specifically "Amendment to follow:" It is our understanding that if the response box is

checked affirmatively, and no amendment is made within the time permitted for amendments, then the prior notice is nullified, or cancelled, and the product will not be allowed to enter the US. If certain elements are amendable, FDA should not need additional advance notice of that fact.

Issue #8 - Different modes of transportation

IDFA is concerned that FDA has not appropriately considered the many different means by which foods enter the United States. IDFA believes that FDA should not rely on a single set of requirements that fail to distinguish differences that air, rail, truck and ocean vessels shipping present. This is especially problematic when one considers the close proximity of sources of imported foods, in particular, Canada and Mexico. A prior notice deadline of noon the day before arrival may work fine for a cargo ship departing from Europe, but it may not make sense for a truck or air shipment from Canada or Mexico, or any number of other countries. IDFA believes that FDA should appropriately address the differences in the final rule.

Issue #9 - Cut off time for prior notices

IDFA does not believe that FDA should be rigid and impose a fixed "noon the day before arrival" prior notice deadline. Instead IDFA suggests that FDA impose a rolling deadline of a certain number of hours prior to arrival sufficiently lengthy to be practical and workable.

As these comments indicate, IDFA's single greatest area of concern lies in the fact that it appears that FDA, has taken a broad based approach to implementing congressional intent and creating a sensible and workable regulation. Alternatively, IDFA urges FDA to pursue a strategy of accomplishing the immediate needs and pursing additional helpful items in the future. With that said, IDFA commends FDA for the job it has done thus far and appreciates the opportunity to comment on the prior notice proposal.

Sincerely,

Clay Detlefsen
Vice President, Regulatory Affairs & Counsel

International Dairy Foods Association
Milk Industry Foundation
National Cheese Institute
International Ice Cream Association

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Re:	Docket No. 02N-0278- Prior Notice of Imported Food	CC:	

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Please see the following from Clay Detlefsen, Vice President and General Counsel, International Dairy Foods Association. Please let us know if we can provide further information.

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